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UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

In Re Bard IVC Filters Products Liability Litigation	No. MD-15-02641-PHX-DGC **PLAINTIFFS' MOTION *IN LIMINE* #1** (Assigned to the Honorable David G. Campbell) **(Oral Argument Requested)**

MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFFS' MOTION IN LIMINE TO EXCLUDE REFERENCE TO FDA 510(k) CLEARANCE AND LACK OF FDA ENFORCEMENT

Plaintiffs seek a pretrial ruling to preclude at trial evidence and argument relating to (1) the FDA's 510(k) clearance of Bard's IVC filters and, (2) evidence on the lack of FDA enforcement against Bard in connection with its filters.

MEMORANDUM OF POINTS AND AUTHORITIES

A. Evidence Relating to FDA 510(k) Clearance is Irrelevant, Misleading and Will Lead to "Mini-Trials"

In previous arguments and trials Bard has attempted to assert an "FDA defense" implying that the FDA's 510(k) clearance process to sell its IVC filters demonstrates (1)

filter safety and effectiveness and (2) Bard's conduct as a manufacturer was reasonable. Bard has also sought to adorn this argument with evidence that the FDA has not taken enforcement action in connection with its IVC filters. But such evidence and argument is irrelevant to the question of whether Bard's IVC filters are safe and effective. And admission of evidence of the FDA's 510(k) clearance of the filters will run the risk of misleading a jury that such clearance is dispositive of Plaintiffs' state law tort claims. Previously, this Court recognized the 510(k) clearance process does not demonstrate safety or effectiveness in that "the 510(k) process does not address product safety and efficacy and therefore is not relevant to Bard's obligations under [state] law." *In re Bard IVC Filters Prod. Liab. Litig.*, 2017 WL 5625547, at *6 (D. Ariz., Nov. 22, 2017) (quoting *Cisson v. C.R. Bard, Inc.*, No. 2:11-cv-00195, 2013 WL 5700513, at *12 (S.D. W.Va. Oct. 18, 2013)(citations omitted)). This holding follows Supreme Court precedent in rejecting the manufacturer's contention that the 510(k) process amounted to a specific federal design requirement or warning requirement protecting and insulating the manufacturer from state law claims. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 498 (1996). As the Supreme Court in *Lohr* held, "The [defendant] exaggerates the importance of the 510(k) process… [T]he 510(k) process is focused on equivalence, not safety… [T]he design of …'substantially equivalent' devices has never been formally reviewed … for safety or efficacy." *Id*. at 493 (emphasis added); *see also Riegel v. Medtronic, Inc*., 552 U.S. 312, 323 (2008) ("While § 510(k) is focused on equivalence, not safety, premarket approval is focused on safety, not equivalence.").

The FDA's decision that an IVC filter is "substantially equivalent" to a predicate device does not tend to prove or disprove any fact at issue with respect to safety or efficacy of the Plaintiffs' IVC filters. Nor does it give rise to any inference that Bard has acted reasonably or its filters were not defective. In other words, the evidence is irrelevant. Fed. R. Evid. 401, 402. Indeed, addressing preemption, this Court found that 510(k) clearance is irrelevant to Plaintiffs' state law claims. *In re Bard IVC Filters*, 2017 WL 5625547, at *6 (quoting *Cisson*, 2013 WL 5700513, at *12)(citations omitted).

Were it relevant, any alleged probative value would be substantially outweighed by the likelihood that this evidence would mislead the jury into thinking that FDA 510(k) clearance *was* probative of Plaintiffs' claims, causing the case to devolve into a series of mini-trials regarding the 510(k) clearance process and Bard's compliance therewith, as well as counter-arguments regarding the alleged meaning of the FDA's enforcement or lack thereof. Fed. R. Evid. 402, 403;[1] *see also Wilson v. Maricopa County*, 2007 WL 686726, at *12-13 (D. Ariz. Mar. 2, 2007) (finding that evidence that creates mini-trials leads to unnecessarily lengthy trials for parties and jury and is precluded under FRE 403) .

Bard should not be permitted to make arguments, present evidence, or otherwise suggest to the jury that its filters have received the FDA's "blessing" to market its retrievable IVC filters despite their known (to Bard) safety issue. In other 510(k)-cleared device cases in which this issue has been raised, courts have routinely found that admission of 510(k) clearance and lack of enforcement evidence is more prejudicial than probative.

> I FIND that evidence as to the FDA's 510(k) process and lack of enforcement action should be excluded under Federal Rule of Evidence 403 because of the danger of misleading the jury, confusing the issues, and unfair prejudice. Given the parties' filings throughout this case, it is abundantly clear that there would be a substantial mini-trial on the 510(k) process and enforcement should it be allowed. In short, this evidence poses a substantial risk of misleading the jury to believe that FDA 510(k) clearance might be dispositive of the plaintiffs' state law claims…
>
> Accordingly, the plaintiffs' motion in limine to exclude all evidence related to the FDA 510(k) process and enforcement is GRANTED … This necessarily means that both parties are precluded from introducing any evidence related to the FDA 510(k) process and enforcement. The evidence would be misleading and its introduction would create a distracting "mini-trial" on FDA compliance, as other courts have recognized.

[1] Argument and evidence on Bard's and the FDA's written and verbal communications also give rise to hearsay issues. Plaintiff does not attempt to predict every document Bard might offer or every argument it might make about FDA actions or communications, so the hearsay issue is not addressed.

In re C.R. Bard, Inc., Pelvic Repair Sys. Prod. ("Cisson"), 2013 WL 3282926, *2 (S.D.W. Va. June 27, 2013) (emphasis in original), *aff'd in part, rev'd in part on other grounds*, *In re C.R. Bard, Inc., MDL. No. 2187, Pelvic Repair Sys. Prod. Liab. Litig.*, 810 F.3d 913 (4th Cir. 2016); *see also In re: Cook Medical Inc., IVC Filters Marketing, Sales Practices and Product Liability Litig. MDL 2570*, No. 1:14-ml-02570-RLY-TAB MDL No. 2570 (S.D. Ind., Sep. 25, 2017).

Furthermore, for Bard to make any representation or create any impression that the 510(k) process determined safety or efficacy—and therefore create confusion as to whether its IVC Filters were FDA-approved as safe and effective—contravenes the FDA's regulations prohibiting a device manufacturer from making "any representation that creates an impression of official approval of a [510(k)] device." 21 C.F.R. § 807.97. Any such representation is "misleading." *Id.* Bard's own Vice President of Regulatory Science, Christopher Ganser, acknowledges this and testified that a 510(k) clearance is not a finding of safety or efficacy. *See* Deposition Testimony of Christopher Ganser, October 11, 2016, Exhibit A, at 57:19-23; 58:5-17.

Excluding evidence of FDA's 510(k) clearance and lack of enforcement is not novel.[2] In the *Cisson* case involving Bard as a defendant, the trial court excluded 510(k) evidence for the reasons Plaintiffs advance here. In its post-trial order, the court commented on the efficiencies realized by excluding the evidence: "[A]llowing 510(k) evidence would

[2] *See Cisson*, 2013 WL 3282926, at *2; *see also Eghnayem v. Boston Sci. Corp.*, 873 F.3d 1304 (11th Cir. 2017) (affirming exclusion of 510(k) evidence of clearance and compliance under FRE 402); *Huskey v. Ethicon*, 848 F.3d 151 (4th Cir. 2017) (affirming exclusion of 510(k) evidence that was substantially outweighed by risks of confusion and wasted time based on FRE 403); *In re: Cook Medical Inc., IVC Filters Marketing, Sales Practices and Product Liability Litig. MDL 2570*, No. 1:14-ml-02570-RLY-TAB MDL No. 2570 (S.D. Ind., Sep. 25, 2017)(excluding FDA 510(k)-related evidence); *In re Zimmer Nexgen Knee Implant Prods. Liab. Litig.*, 2015 WL 5145546, at *14 (N.D. Ill. Aug. 31, 2015) (excluding 510(k) process because "there is significant risk the jurors may be led to believe that the 510(k) clearance that Zimmer's NexGen Flex system components received is equivalent to a finding of non-negligent design, which is an incorrect statement of law."); *Lewis v. Johnson & Johnson*, 991 F. Supp. 2d 748, 754-755 (S.D.W.Va. 2014) (finding probative value of evidence of FDA 510(k) clearance or subsequent FDA enforcement actions was substantially outweighed by prejudicial effect).

have provoked the parties to engage in a time-consuming mini-trial on whether Bard in fact complied with its provisions. Excluding 510(k) evidence avoided these risks and was therefore proper under Rule 403." *Cisson v. C.R. Bard, Inc*., 86 F. Supp. 3d 510, 517–18 (S.D. W.Va. Jan. 20, 2015), *aff'd, In re C.R. Bard, Inc., MDL. No. 2187, Pelvic Repair System Prod. Liab. Litig.*, 810 F.3d 913 (4th Cir. 2016). Bard claimed there would have been no mini-trial. The trial court disagreed, *id*. at 518 n.7 ("Although Bard asserts such a mini-trial would not have developed, the back-and-forth on this issue both prior to and after trial has justified my fears."), and the Fourth Circuit affirmed, *In re C.R. Bard, Inc., Pelvic Repair Sys.*, 810 F.3d at 921 ("[B]ald assertions by the FDA do little to alter the analysis of the basic question: How much information does 510(k) clearance provide a jury about the safety of the underlying product?); *see also Winebarger v. Boston Sci. Corp.*, 2015 WL 5567578, at *7 (W.D. N.C. Sept. 22, 2015) ("[T]he risk of misleading and confusing the jury is also great. A mini-trial on the FDA 510(k) clearance process would be a waste of time.").

The same risk of lengthy mini-trial issues exists here. For example and similar to the trial court's opinion in *Cisson*, Bard's preemption motion based on 510(k) clearance was filed in March 2017, yet after substantial discovery directed solely at that issue the parties' briefing on issues related to the FDA's role and involvement, motion practice did not end until December 2017; the back-and-forth prior to the Court's ruling, and after, exemplifies the potential for a trial within a trial. Moreover, the Court recognized this potential in its opinion describing the enormous record Bard finds imperative to its case which ultimately is not related to whether the devices at issues are safe and effective: "Bard has submitted more than 800 factual paragraphs to illustrate its extensive communications with the FDA concerning the seven generations of filters at issue in this case. Doc. 5398. But the Court agrees with Plaintiffs' suggestion that these communications merely reflect the back-and-forth of 510(k) review." *In re Bard IVC Filters Prod. Liab. Litig.*, 2017 WL 5625547, at *11.

Therefore, in the instant case, exclusion of FDA clearance and lack of enforcement evidence will greatly reduce the amount of evidence and regulatory expert testimony necessary to explain the 510(k) clearance process as to Bard's IVC filters. It would also eliminate the need for testimony from witnesses as to the pre-market 510(k) clearance process,[3] including clearance-related testimony from Kay Fuller, Mary Edwards and possibly others. Expert testimony regarding FDA 510(k) issues would become unnecessary eliminating days from a trial as the parties regulatory witnesses would likely take a day each for direct and cross-examination if required to testify about the clearance process and what it means, i.e., presenting arguments that FDA clearance does not indicate the device is safe or effective. Also, other than as to potential issues such as notice, evidence and testimony regarding the FDA "Warning Letter" would most likely be unnecessary.[4]

B. Lack of FDA Enforcement Action Should Be Excluded As Irrelevant and Immaterial.

Bard would like to argue to the jury that lack of FDA enforcement actions against its IVC filters is evidence of the filters' safety and efficacy and the reasonableness of its conduct. The inference it would have the jury draw from lack of enforcement would be speculative, misleading, and highly prejudicial. Also, the FDA's lack of enforcement does not support an inference that Bard filters are safe or that Bard has acted reasonably. "The 510(k) process is not a safety statute or administrative regulation." *Lewis*, 991 F. Supp. 2d at 754-755. The assertion that the FDA never took enforcement action was also addressed in *Lohr*, where the Court noted that "[t]he FDA's authority to require manufacturers to recall, replace, or refund defective devices is of little use to injured plaintiffs, since there is no indication that the right is available to private parties, the remedy would not extend to

[3] Plaintiffs' position is that pre-market evidence such as Bard's testing results and evidence going to Bard's knowledge is relevant, yet pre-market evidence regarding the actual 510(k) clearance process is separate and should be inadmissible.

[4] On December 15, 2017, the Court queried Plaintiffs on these particular evidentiary issues, and both parties regarding the length of the first bellwether trial which is now limited to eleven days. Based on previous Bard IVC trial experience, Plaintiffs feel strongly that if this motion seeking exclusion of certain FDA evidence is not granted, the time limitations will be prohibitive.

recovery for compensatory damages, and the authority is rarely invoked, if at all." 518 U.S. 470, 487, n.7.

Moreover, the knowledge, motivations, intent, state of mind, and purposes of the FDA or FDA officials are inadmissible. *See, e.g., In re Fosamax Prod. Liab. Litig.*, 645 F. Supp. 2d 164, 192 (S.D.N.Y. 2009). Any suggestion or argument based on why the FDA did not take enforcement action against Bard relative to its IVC filters would impermissibly invite the jury to speculate as to what the FDA intended or what the agency or its employees were thinking or aware of. Bard cannot suggest to the jury that it draw inferences with respect to the safety and efficacy of its IVC filters from the FDA's inaction or from its regulatory authority in general and Bard's own experts agree that such testimony would require speculation.

> Q. Was FDA advised -- well, let me ask you, what -- what effect on the clearance of the Recovery filter do you think it would've had on whoever was looking at the 510(k) application for the Recovery filter had he or she known that the investigator thought that all the patients should be advised of the circumstances of that migration before the study could continue?
>
> A. Personally?
>
> Q. Yeah.
>
> A. I don't believe it would have had much of an impact. Fracture was a well-known risk for IVC filters, and the event was clearly described in the 510(k) application. If anything, I think that -- you know, at least if I had been at FDA, I would have been happy to see that some precautionary steps were taken.
>
> Q. Okay. That's your opinion, I understand. But you can't tell me what effect that would have had on the actual person looking at the application, true?
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> A. You're correct, sir, I cannot speculate on what any individual would do or not do.
>
> Q. I would have to ask him or her.
>
> A. Yes, sir.

See Deposition Testimony of Christine Brauer (Bard's Regulatory Expert), August 2, 2017, Exhibit B, 127:21-128:21).

Additionally, Plaintiffs would be unfairly prejudiced, and the jury would be misled and confused, by any suggestion that the FDA's lack of enforcement action signifies product safety. *See, e.g.*, *Lewis*, 991 F. Supp. 2d at 755 ("[A]dmission of evidence regarding FDA enforcement actions against Ethicon (or the lack thereof) runs the same risk of misleading the jury as the 510(k) clearance process. Jurors are likely to believe that FDA enforcement relates to the validity of the plaintiffs' state law tort claims, which it does not."). If anything, FDA's lack of enforcement action signifies its inability to police companies like Bard. *See Wyeth v. Levine*, 555 U.S. 555, 578-79 (2009) (observing that manufacturers have more resources and more knowledge of their products than does FDA); U.S. Gen. Accounting Office, GAO-09-370T, *Shortcomings in FDA's Premarket Review, Postmarket Surveillance, and Inspections of Device Manufacturing Establishments* 1 (2009) ("[S]hortcomings in both premarket and postmarket activities raise serious concerns about FDA's regulation of medical devices... [R]ecently, concerns have been expressed about FDA's ongoing ability to fulfill its mission of ensuring the safety and efficacy of medical products, including drugs, biologics, and devices.").

Thus, Bard's intended use of evidence on lack of FDA enforcement action is based on speculation and would mislead the jury. It also would require its own "mini-trial" on the FDA regulatory enforcement scheme and the FDA's enforcement resources.

C. Conclusion

Accordingly, Plaintiffs respectfully request that this Court enter an Order (1) granting this motion; (2) prohibiting at trial all evidence and argument relating to the 510(k) clearance process; and (3) prohibiting at trial all evidence and argument regarding the FDA's lack of enforcement action as to Bard's IVC filters.

RESPECTFULLY SUBMITTED this 2nd day of January 2018.

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CERTIFICATE OF SERVICE

I hereby certify that on this 2nd day of January 2018, I electronically transmitted the attached document to the Clerk's Office using the CM/ECF System for filing and transmittal of a Notice of Electronic Filing.

/s/ Gay Mennuti